DEC 30 2011

510(k) Summary of Safety and Effectiveness for the Dimension Vista® LOCI 9 Calibrator (KC647)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K113373

B. Date of Preparation: October 28, 2011

C. Proprietary and Established Names:
Dimension Vista® LOCI 9 Calibrator, LOCI 9 CAL (KC647)

D. Applicant:
Siemens Healthcare Diagnostics Inc., P.O. Box 6101, Newark, DE 19714-6101
Frances A. Dillon, Regulatory Affairs & Compliance Manager
Office: (302) 631-6951 Fax: (302) 631-6299

E. Regulatory Information:
Dimension Vista® LOCI 9 Calibrator, LOCI 9 CAL (KC647)
1. Regulation section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIT – Calibrator, Secondary
4. Panel: Clinical Chemistry

F. Predicate Device:
The predicate device used to demonstrate substantial equivalence is the Dimension Vista® N-terminal Pro-Brain Natriuretic Peptide Calibrator, PBNP CAL (KC676A), cleared under K080578.

G. Device Description:
The LOCI 9 Calibrator is a liquid, frozen bovine serum albumin based product packaged as ten vials to a carton, with two vials at each of the 5 levels (A, B, C, D and E), 1.5 mL per vial. The LOCI 9 Calibrator includes progesterone, testosterone, buffers and preservatives.

Note: Although testosterone is present in this formulation, the LOCI 9 Calibrator will only be used with the Dimension Vista® Progesterone assay.

H. Intended Use:
The LOCI 9 CAL is an *in vitro* diagnostic product for the calibration of the progesterone (PROG) method on the Dimension Vista® System.

I. Substantial Equivalence Information:
The Dimension Vista® LOCI 9 Calibrator, LOCI 9 CAL (KC4647) was compared to the predicate device, Dimension Vista® N-terminal Pro-Brain Natriuretic Peptide Calibrator, PBNP CAL (KC676A), cleared under K080578. The following tables provide a comparison of the important similarities and differences between the devices:

Similarities

Feature	New Device Dimension Vista® LOCI 9 Calibrator, LOCI 9 CAL (KC647)	Predicate Dimension Vista ® N-terminal Pro-Brain Natriuretic Peptide Calibrator, PBNP CAL (KC676A)
Intended Use	For in vitro diagnostic use.	For in vitro diagnostic use..
Matrix	Bovine serum albumin based	Bovine serum albumin based
Form	Liquid, frozen	Liquid, frozen
# Levels	Ten vials, two vials per level, 5 levels (A, B, C, D and E)	Ten vials, two vials per level, 5 levels (A, B, C, D and E)

Differences

Feature	New Device Dimension Vista® LOCI 9 Calibrator, LOCI 9 CAL (KC647)	Predicate Dimension Vista ® N-terminal Pro-Brain Natriuretic Peptide Calibrator, PBNP CAL (KC676A)
Intended Use	The LOCI 9 CAL is an *in vitro* diagnostic product for the calibration of the progesterone (PROG) method on the Dimension Vista® System.	The PBNP CAL is an *in vitro* diagnostic product for the calibration of the N-terminal Pro-Brain Natriuretic Peptide (PBNP) method on the Dimension Vista® System.
Analyte	Progesterone	Synthetic PBNP
Volume	1.5 mL per vial	1.0 mL per vial
Typical Concentration Levels	Five Levels, (0, 1.0, 8.0, 20.0 and 44.0 ng/mL)	Five levels, (0, 250, 1500, 12,000 and 36,750 pg/mL)

J. Performance:

The traceability, value assignment and stability of the Dimension Vista® LOCI 9 Calibrator have been validated following procedures of Siemens Healthcare Diagnostics, Inc.

K. Conclusion:

The Dimension Vista® LOCI 9 Calibrator (KC4647) is substantially equivalent in design and intended use to the previously cleared Dimension Vista® N-terminal Pro-Brain Natriuretic Peptide Calibrator (KC676A).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc.
c/o Frances A. Dillon
P.O. Box 6101
Mailstop 514
Newark, DE 19714-6101 USA

DEC 30 2011

Re: k113373
Trade Name: Dimension Vista® LOCI 9 Calibrator
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT
Dated: November 15, 2011
Received: November 16, 2011

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):
K113373

Device Name:

Dimension Vista® LOCI 9 Calibrator

Indications for Use:

The LOCI 9 CAL is an *in vitro* diagnostic product for the calibration of the progesterone (PROG) method on the Dimension Vista® System.

Prescription Use __X_____ and/or Over-the-counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113373